

Office of Industrial Affairs

September 14, 1998

RE: Provisional Patent Application for Memorial Sloan Kettering Cancer Center

VIA OVERNIGHT MAIL

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

Dear [REDACTED]

The Office of Industrial Affairs at Memorial Sloan-Kettering Cancer Center would like to retain you for the filing of a patent application for a new technology, tentatively entitled: *Anti-resorptive allograft bone and bone cement*. Enclosed please find two invention disclosure forms and a section of a grant application that describe this technology.

[REDACTED]

[REDACTED] If you require any additional information, please contact me at the telephone number below. I look forward to speaking with you.

Sincerely,

[REDACTED]

Office of Industrial Affairs
Memorial Sloan-Kettering Cancer Center

Enclosures (3)

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Memorial Sloan-Kettering Cancer Center
1275 York Avenue, New York, New York 10021
Telephone 212.639.6181 • FAX 212.717.3439

NCI-designated Comprehensive Cancer Center



Memorial Sloan-Kettering Cancer Center

INVENTION DISCLOSURE FORM

File No. SK 848

(File No. completed by Office of Industrial Affairs)

This form is provided to help organize your thoughts about your invention. Be careful to describe what, specifically, makes your invention different from what has been invented before. Avoid general statements that your invention is "Better" - why is it better, or what makes it better?

1) *Descriptive Title of Invention: Osteolysis resistant bone cement*

2) *Description of Invention: mixture of bisphosphonates into bone cement*

a) State as fully as possible, what the invention is, including:

- *materials or components used. acrylic bone cement and bisphosphonates*
- *operative and preferred ranges of process parameters and concentrations of chemical compounds. under development*
- *foreseeable uses of the invention Bone cement is used to grout most orthopaedic joint replacements. The greatest problem plaguing the durability of the implant fixation is aseptic loosening. This is induced by particulate debris shed from the implant and is mediated by osteoclastic bone resorbing cells. Bisphosphonates block this resorption. Potentially all joint replacements would be secured with cement containign bisphosphonates to prevent osteolysis and prosthetic failure.*

b) Records Supporting Invention. [REDACTED]

Identify records which establish dates of conception and reduction to practice, including identity of person who prepared record and its present location. Attach copies if possible. Note additional supporting evidence. If the invention or a significant aspect of the invention is not supported by written records, briefly describe how the date of invention can be established and identify earliest written record.

c) Fill in the following dates:

- Conception [REDACTED] 1997

- First disclosure to another [REDACTED]

- First written record [REDACTED]

■ First experiment demonstrating the invention ___ none

d) This invention is a(n): ___ process ___ chemical compound ___ X ___ therapeutic method ___ electronic circuit ___ X ___ mixture of chemical compounds ___ apparatus ___ other ___ +/-

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- e) The problem which this invention solves is: Local delivery of antiresorptive agents to retard the development of osteolysis, thereby potentially extending the useful life of joint replacements

The closest prior art is: (* Please attach copies of relevant publications Systemic delivery of bisphosphonates has been done experimentally to address this problem of osteolysis. No local delivery system has been used to my knowledge.

Antibiotics have been mixed into cement to treat bone and periprosthetic infection. Antineoplastic drugs (methotrexate, cis platinum) have been used experimentally and anecdotally for clinical indications.

- g) This invention differs from the closest prior art in that: It is the first local delivery system for this class of drug or for this clinical indication.

h) This invention provides the following advantages: It is easy to perform. The cement can be produced with bisphosphonate admixed or the surgeon could prepare it at the time of use in the operating room. It combats the greatest problem reducing the longevity of joint replacements.

i) This invention possesses the following disadvantages or limitations (*describe how they can be overcome if applicable*). It is unknown how long the drug will leech out of the cement and exert its local effect. Consequently, it may be absent when the problem of osteolysis starts, several years after prosthetic implantation.

However, even if the drug has left the cement, it may permanently adsorb to the adjacent bone. Its effect may be exerted on an ongoing basis.

- j) Has the invention or any project derived therefrom been:

1. Described in a printed publication. no _____ Date _____
2. Described in an oral presentation. no _____ Date _____
3. Sold, offered for sale, or used in public? no _____ Date _____
4. Are any of 1 through 3 contemplated in the near future and, if so, when?

_____ whenever I have sufficient data _____

(If the answer to any of 1 through 4 is YES, provide detailed information, including copies of manuscripts, published articles, abstracts, etc., together with a floppy disk containing the text of any of your manuscripts, papers or abstracts, etc. that describe the invention. Please indicate the word processing software, version and system [e.g., Wordperfect 5.1, 6.1, 7.0 or MSWord 7.0 ; RTF; or TXT; IBM].)

- 3) NCI Core Grant No. 08748. Other Grant(s)/Contract(s) (VERY IMPORTANT IF APPLICABLE):

Sponsor _____ Award No. _____

Principal Investigator _____

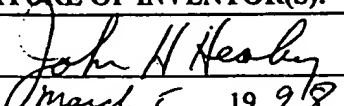
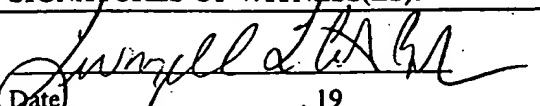
- 4) Lab/Department where developed: Orthopaedic surgery

5) Contractual Agreements with Other Parties (include name of person contacted and copies of pertinent agreements): none

6) Who contributed to the invention or discovery? Please identify all colleagues who could merit co-authorship credit for the associated publication:

Name _____ none _____	Ext. 7610 _____
Home Address _____	Dept. Orthopaedics _____
_____	Phone No. () _____
_____	Citizenship _____
Name _____	Ext. _____
Home Address _____	Dept. _____
_____	Phone No. () _____
_____	Citizenship _____
Name _____	Ext. _____
Home Address _____	Dept. _____
_____	Phone No. () _____
_____	Citizenship _____
Name _____	Ext. _____
Home Address _____	Dept. _____
_____	Phone No. () _____
_____	Citizenship _____
Name _____	Ext. _____
Home Address _____	Dept. _____
_____	Phone No. () _____
_____	Citizenship _____

(Include additional names along with the above information on a separate sheet.)

SIGNATURE OF INVENTOR(S):	SIGNATURES OF WITNESS(ES):
	
Date March 5, 1998	Date _____, 19____
_____	_____
Date _____, 19____	Date _____, 19____
_____	_____